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ATTORNEY DOCKET NO. 19141.0016U2
PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Eppstein, *et al.*	)	
	)	Group Art Unit: Unassigned
Serial No. 10/084,763	)	
	)	
Filed: February 21, 2002	)	Examiner: Unassigned
	)	
For: **"INTEGRATED TISSUE PORATION, AND FLUID HARVESTING"**	)	

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

April 15, 2002

Sir:

Transmitted herewith are the following:

1. Request for First Interference Pursuant to 37 C.F.R. 1.607;
2. Request for Second Interference Pursuant 30 37 C.F.R. 1.607;
3. Certificate of Express Mail EL924194186US dated April 15, 2002; and
4. Postcard.

No fee is believed to be due; however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

William R. Johnson
Registration No. 32,875

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CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail No. EL924194186US in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date indicated below.

David Thorpe

4-15-02
Date

W135221

ATTORNEY DOCKET NO. 19141.0016U2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Eppstein, *et al.*	)	
	)	Group Art Unit:
Serial No. 10/ 084,763	)	
	)	
Filed: February 21, 2002	)	Anticipated Examiner: P. Wingood
	)	
For: **"INTEGRATED TISSUE PORATION, AND FLUID HARVESTING"**	)	

REQUEST FOR FIRST INTERFERENCE PURSUANT TO 37 CFR 1.607

Assistant Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

April 15, 2002

Sir:

In accordance with the provisions of 37 C.F.R. §1.607, Applicants request that an interference be declared between this application and four unexpired U.S. patents, i.e., U.S. Patent Nos. 6,063,039; 6,155,992; 6,206,841; and 6,283,926.

In accordance with the 37 C.F.R. §1.607(a)(1)-(a)(6), Applicants offer the following:

(1) The patents at issue are:

a. U.S. Patent 6,063,039 issued May 16, 2000;

b. U.S. Patent 6,155,992 issued December 5, 2000;

c. U.S. Patent 6,206,841 issued March 27, 2001

d. U.S. Patent 6,283,926 issued September 4, 2001.

Each of the patents in question is assigned, on its face, to Abbott Laboratories.

(2) The proposed count is as follows:

Claims 1, 2, 51, 52, 55, 57, 61, 62, 63 or 64 of this application; or Claims 1, 15, 17, 18, 30, 45, 46, or 47 of U.S. Patent 6,063,039; or Claim 1, 18 or 32 of U.S. Patent 6,155,992; or Claims 1, 4 or 7 of U.S. Patent 6,206,841; or Claim 1 of U.S. Patent 6,283,926.

(3) The following claims in the patents correspond to the proposed count:

a. Claims 1-58 of U.S. Patent 6,063,039;

b. Claims 1-32 of U.S. Patent 6,155,992;

c. Claims 1-9 of U.S. Patent 6,206,841; and

d. Claims 1-18 of U.S. Patent 6,283,926.

(4) Claims 1-4, 32, and 49-64 of this application correspond to the proposed count;

(5) The terms in claims in this application identified as corresponding to the count can be applied to Applicants' specification as shown in Appendix I attached hereto.

(6) Applicants have met the requirements of 35 U.S.C. 135(b):

a. As to U.S. Patent 6,063,039, attention is directed to Claims 175-232 filed in a Preliminary Amendment of parent application Serial No. 09/263,464 on March 15, 2001 in which each claim of the '039 patent was copied;

b. As to U.S. Patent 6,155,992, attention is directed to Claims 143-174 filed in a Preliminary Amendment filed in parent application Serial No. 09/263,464 on March 15, 2001 in which each claim of the '992 patent was copied.

c. As to U.S. Patent 6,206,841, attention is directed Claims 51-54 filed in the Preliminary Amendment dated March 27, 2002, in this application.

In considering 35 USC 135(b), Applicants would point out that each of the claims in the '039 patent and the '992 patent were copied into the parent application Serial No. 09/263,464 on March 15, 2001, which date is prior to the one year anniversary of issuance of either of the two patents. Attention is further directed to the claim chart appearing in Appendix II where the present claims 1-4 are compared with the claims 143, and 204, which claims were offered in parent application 09/263,464 on March 15, 2001. Finally, as to the '841 patent, Applicants offered Claims 51-54 on March 27, 2002, which was the one year anniversary of issuance of the '841 patent. Thus, the requirements of 35 USC 135(b) have been met.

Applicants hereby request benefit of the effective filing date of November 15, 1993 in the declaration of interference as evidenced by the disclosure in their prior applications[1]. In connection with this effective filing date, Applicants would point out:

First, Applicants are entitled to benefit of their earlier filed applications for purposes of this interference, if the count reads on at least one adequately disclosed embodiment in the earlier application. Weil v. Fritz, 572 F.2d 856, 865-66 n.16, 196 USPQ 600, 608 n.16 (CCPA 1978).

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[1] This application is the latest in a chain of applications which include U.S. application Serial No. 09/570,334, filed May 15, 2000, U.S. application Serial No. 09/208,166, filed December 9, 1998 (now U.S. Patent No. 6,142,939), U.S. application Serial No. 08/776,863, filed September 5, 1997 (now U.S. Patent No. 5,885,211), U.S. application Serial No. 08/520,547, filed August 29, 1995 (now abandoned), U.S. application Serial No. 08/152,442, filed November 15, 1993 (now U.S. Patent No. 5,458,140). This application is also the latest in a chain of applications which include U.S. application Serial No. 08/152,174, filed December 8, 1993 (now U.S. Patent No. 5,445,611); and U.S. Provisional Application No. 60/008,043, filed October 30, 1995. Finally, this application is also the latest in a chain of applications including U.S. application Serial No. 09/263,464, filed March 5, 1999, and U.S. Provisional Application No. 60/077,135, filed March 6, 1998.

Evidence of this, involving Claim 61 and the '140 patent that issued from application Serial No. 08/152,442 filed November 15, 1993, is provided in Appendix III to this request.[2]

Second, as to the requirements of 37 C.F.R. §1.608, the effective filing date, i.e., November 15, 1993, of the present application is more than three years **earlier** than the effective filing date of the earliest of the three patents in question, i.e., December 6, 1996 (U.S. Patent 6,063,039). Accordingly, Applicants submit that no showing under 37 C.F.R. §1.608 is required.

Third, in light of their earlier effective filing date, Applicants should also be designated as the senior party in the interference.

As a final matter, should the Examiner have any questions regarding this paper, or the application in general, he is invited to telephone the undersigned at his earliest convenience. No fee is believed due. However, the Commissioner is hereby authorized to charge any fees that may be required to the Deposit Account No. 14-0629.

Respectfully submitted,

William R. Johnson
Registration No. 32,875

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David Thorpe — Date: 4-15-02

[2] The citations are offered in connection with the '140 patent solely due to the relative ease of citing to column and line in the patent, however, all pertinent disclosure was present in the '442 application as filed.

Appendix I- 37 CFR 1.607(a)(5)

Applicants' Claims corresponding to the proposed count.	**Exemplary Disclosure in Applicants' Specification**
1. A method for obtaining interstitial fluid for diagnostic testing comprising:	"One aspect of the invention relates to methods for obtaining biological fluids for analysis/testing." Page 4, lines 6 - 7. "In still another embodiment, the method comprises ...collecting the interstitial fluid, and analyzing the analyte in the collected interstitial fluid." Page 6, lines 27-29.
(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;	"Porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte." Page 4, lines 14 - 16. "[T]he method comprises ablating the stratum corneum such that interstitial fluid exudes from the micropores collecting the interstitial fluid, and analyzing the analyte in the collected interstitial fluid." Page 6, lines 27-29.
(b) collecting a sample from the opening,	"...collecting the interstitial fluid...." Page 6, lines 28-29.
wherein step (b) is enhanced by applying a vacuum to the selected area of the skin.	"Preferably, vacuum can be applied to the porated selected area to enhance collection of interstitial fluid." Page 7, lines 3-4.

2. A method for obtaining biological fluid for diagnostic testing comprising:	"Among other aspects, the present invention relates to methods for obtaining samples of biological fluids, including blood and interstitial fluid, for diagnostic analysis/testing..." Page 4, lines 2-4. "One aspect of the invention relates to methods for obtaining biological fluids for analysis/testing." Page 4, lines 6 - 7.
(a) forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;	"...forming at least one hole in the tissue; collecting biological fluid from the tissue through at least one opening in the layer; and wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid. The at least one opening in the tissue is created by any of a variety of poration techniques, including thermal ablation, laser ablation, direct absorption ablation or mechanically creating a hole in the tissue with a mechanical porating element." Page 4, line 22- page 5, line 1. "The photothermal material 240 is responsive to the optical energy transfer heat to the surface of the tissue to form one or more micropores therein." Page 32, lines 26 - 28. "The microprocessor 200 may continue the delivery of sonic energy until the fill monitor circuit 82 detects that the integrated device 200 has collected sufficient biological fluid to make an accurate assay measurement." Page 33, lines 12-14.
(b) extracting the sample from the opening,	"...collecting biological fluid from the tissue through at least one opening in the layer..." Page 4, lines 22-23.

wherein at least one of positive and negative pressure are employed in order to enhance the extraction of the sample.	"Likewise, positive pressure may be applied to the integrated device 100 to force fluid to move towards the sensor 120." Page 27, lines 22-24. "Further, vacuum (negative pressure) may be applied to the microporated site to assist in the harvesting of the biological fluid." Page 27, lines 20-21.
3. The method of claim 2 wherein the biological fluid comprises blood.	"As used herein, the expression 'biological fluid' is intended to include blood." Page 16, line 20.
4. The method of claim 2 wherein the biological fluid comprises interstitial fluid.	"As used herein, the expression 'biological fluid' is intended to include blood, e.g., blood serum or whole blood, as well as interstitial fluid." Page 16, lines 20-21.
2. The combination of claim 64, and further omprising a sealed electrical connection to the ensor and/or probe via the sealing means.	"In addition, if an integrated device is used that requires connection to an electrode on the sensor and/or probe, this connection is made through a sealed electrical connector 810 in the top layer 804." Page 46, lines 18-21.
9. The method of claim 62, and further omprising the step of forming a sealed hamber over the layer and the sensor.	"A sealed chamber 806 is formed in the space between the integrated device and the top layer 804." Page 46, lines 13-14.
50. The method of claim 2, wherein the characteristic of the biological fluid is the concentration of glucose.	"Glucose is a specific example of an analyte because it is a sugar suitable for passage through the skin, and individuals, for example those having diabetes might want to know their blood glucose levels." Page 16, line 26 - Page 17, line 1.
51. A method for harvesting interstitial fluid from tissue and analyzing the interstitial fluid, comprising steps of: (a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;	"[T]he method comprises ablating the stratum corneum such that interstitial fluid exudes from the micropores, collecting the interstitial fluid, and analyzing the analyte in the collected interstitial fluid." Page 6, lines 27-29.
(b) collecting the sample from the skin opening,	"...collecting the interstitial fluid,..." Page 6, lines 28-29.

wherein step (b) is enhanced by applying a vacuum to the selected area of the skin,	"Preferably, vacuum can be applied to the porated selected area to enhance collection of interstitial fluid" Page 7, lines 3-4.
and further wherein the sample is collected in an article comprising (i) a pad capable of receiving an interstitial fluid sample; and (ii) a strap or adhesive tape for holding the pad to the selected area of the skin,	"[A] device that can be utilized for the application of sonic energy and collection or [sic] analyte comprises an absorbent pad, either of natural or synthetic material, which serves as a reservoir for the chemical enhancer, if used, and for receiving the analyte from the skin surface. The pad or reservoir is held in place, either passively or aided by appropriate fastening means, such as a strap or adhesive tape, on the selected area of skin surface." Page 104, lines 5-10.
wherein the article contains an opening suitable to allow the sample to contact the pad; and	"The lower section 2222 contains an opening through which glucose may pass from the skin to the interior of the device 2206" Page 105, lines 5-6.
(c) determining the amount of analyte within the sample.	"...and analyzing the analyte in the collected interstitial fluid." Page 6, line 29.
52. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising:	"In addition, the present invention includes methods for harvesting biological fluid from tissue and analyzing the biological fluid" page 4, lines 21-22.
(a) providing a multi-layer integrated device comprising:	"As used herein, the term "integrated device" means a device suitable for forming small holes or micropores in tissue, collecting a biological fluid from the tissue (preferably through the micropores so created) and analyzing the biological fluid to determine a characteristic thereof." Page 18, lines 24-27.
(i) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;	"One embodiment of a multi-layer integrated device comprises (a) a receiving layer capable of receiving a biological fluid including an analyte and facilitating the movement of the fluid..." Page 9, lines 11-13.

(ii) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;	"...(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;" Page 9, lines 13-14 "An analyte sensor 120 is disposed on the under-surface of the substrate layer 110." Page 24, lines 21-22.
(iii) a substrate layer that is capable of being in contact with a processing circuit, and	"...and (c) a substrate layer that is in contact with a processing circuit, wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the sensor (b); and further wherein said substrate layer (c) has at least one opening therein." Page 9, lines 14-18. "The integrated device 100 has electrode leads 122 that connect to the analyte sensor 120 and to a processing circuit 20." Page 24, lines 23-24. *See also* Fig. 1.
(iv) a bottom layer; wherein the receiving layer (i) is located underneath at least a portion of the substrate layer (iii) and wherein said substrate layer (iii) has at least one opening therein;	"...(d) a bottom layer; wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the sensor (b); and further wherein said substrate layer (c) has at least one opening therein." Page 9, lines 23-26 "A layer of photothermal material 130 is located on the bottom surface of the substrate 110." Page 24, lines 25-26. "The integrated device 100 comprises a substrate layer 110 that includes an optically transparent window 112 on at least a portion thereof." Page 24, lines 19-21.

(b) forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;	"The photothermal material 240 is responsive to the optical energy transfer heat to the surface of the tissue to form one or more micropores therein." Page 32, lines 26 - 28. "The microprocessor 200 may continue the delivery of sonic energy until the fill monitor circuit 82 detects that the integrated device 200 has collected sufficient biological fluid to make an accurate assay measurement." Page 33, lines 12-14.
(c) extracting the sample from the skin opening and introducing the sample into the integrated device,	"More specifically, the micropore M can permit interstitial fluid in the tissue to flow into the integrated device 100 and eventually to contact the sensor 120." Page 26, lines 4-5.
wherein at least one positive and negative pressure is employed in order to enhance the extraction of the sample; and	"Likewise, positive pressure may be applied to the integrated device 100 to force fluid to move towards the sensor 120." Page 27, lines 22-24. "Further, vacuum (negative pressure) may be applied to the microporated site to assist in the harvesting of the biological fluid." Page 27, lines 20-21.
(d) measuring a characteristic of the biological fluid.	"The processing circuit 20 is any well known glucose measuring circuit that is capable of measuring the output of an electrochemical analyte sensor and producing a reading correlated to the concentration of a target analyte in biological fluid, such as glucose." Page 26, lines 7-10.
53. The method of claim 52 wherein the biological fluid comprises blood	"As used herein, the expression 'biological fluid' is intended to include blood." Page 16, line 20.
54. The method of claim 52 wherein the biological fluid comprises interstitial fluid.	"As used herein, the expression 'biological fluid' is intended to include blood, e.g., blood serum or whole blood, as well as interstitial fluid." Page 16, lines 20-21.

55. An apparatus for obtaining biological fluid for diagnostic testing comprising: (a) a device for forming an opening in an area of skin suitable for extracting a sample comprising interstitial fluid;	"The integrated device 100 and all other specific embodiments described hereinafter, are designed to form micropores in tissue, collect fluid from the tissue, and analyze the fluid in a single (integrated) step." Page 25, lines 12 - 14.
(b) a vacuum device for introducing a vacuum onto the selected area of skin so as to enhance fluid flow from the skin, wherein the device is capable of controlling the pressure level and/or timing of the vacuum.	"A vacuum port 808 is provided in the top layer 804 for connection to a means for supplying negative pressure, such as a pump 820." Page 46, lines 14 - 16.
56. The apparatus according to claim 55 wherein the vacuum is capable of being maintained at a desired pressure level.	"A vacuum port 808 is provided in the top layer 804 for connection to a means for supplying negative pressure, such as a pump 820." Page 46, lines 14 - 16.
57.An apparatus for obtaining biological fluid for diagnostic testing comprising: (a) a device for forming an opening in an area of skin suitable for extracting a sample of biological fluid;	"The integrated device 100 and all other specific embodiments described hereinafter, are designed to form micropores in tissue, collect fluid from the tissue, and analyze the fluid in a single (integrated) step." Page 25, lines 12 - 14.

(b) a mechanical device for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening, wherein the device is capable of controlling the timing and/or the amount of pressure on the skin.	"A mechanical element 850 is provided, having a small opening 852, 2 mm to 4 mm in diameter. The mechanical element 850 permits the integrated device to slide between two opposing surfaces and contains the integrated device. Applying force to the mechanical element 850 presses the integrated device onto the skin at the poration site and thus creates a positive pressure gradient in the biological fluid harvested from the tissue TS, i.e., the skin, forcing it towards the micropores where it can exit the tissue and enter the inlet port(s) of the fluid management chamber of the integrated device (100, 200, 300, 400, 600, 1000). The tissue bulges into the opening 852 as shown in FIG. 18. A close registration is maintained between the inlet ports to the integrated device and the micropores, which have been, or simultaneously will be, formed in the tissue directly beneath these ports. The mechanical device 850 may be optically clear on its top portion to allow for optical thermal ablation and optical reading of the photometric sensor in that form of the integrated device. The application of mechanically induced pressure may be continuous, modulated, as in a sine or triangle wave, or pulsed." Page 47, line 25- page 48, line 11.
58. The apparatus according to claim 57 further comprising a vacuum device for introducing a vacuum onto the selected area of skin so as to enhance fluid flow from the opening, wherein the device is capable of controlling the pressure level and/or timing of the vacuum.	"In addition, the use of the mechanical device may be combined with vacuum to provide an additional biological fluid forcing function, and to possibly assist in the fluid management of the biological fluid as it exits the body." Page 48, lines 18-21 "A vacuum port 808 is provided in the top layer 804 for connection to a means for supplying negative pressure, such as a pump 820." Page 46, lines 14 - 16.

59. The apparatus of claim 57 wherein the sample comprises blood.	"As used herein, the expression "biological fluid" is intended to include blood, e.g. blood serum or whole blood, as well as interstitial fluid." Page 16, lines 20 - 21.
60. The apparatus of claim 57 wherein the sample comprises interstitial fluid.	"As used herein, the expression "biological fluid" is intended to include blood, e.g. blood serum or whole blood, as well as interstitial fluid." Page 16, lines 20 - 21.
61. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:	"One aspect of the invention relates to methods for obtaining biological fluids for analysis/testing." Page 4, lines 6 - 7.
(a) placing a layer in contact with a surface of tissue; (b) forming at least one hole in the tissue;	"Porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte." Page 4, lines 14 - 16 "A sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collection from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 24 - 26.
(c) collecting biological fluid from the tissue through at least one opening in the layer; and	"A sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collection from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 24 - 26.

(d) wetting a sensor with biological fluid to measure a characteristic of the biological fluid, wherein the process further comprises applying positive pressure to the layer so as to induce flow of biological fluid through the opening.	"Wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid." Page 4, lines 22 - 24. "Applying force to the mechanical element 850 presses the integrated device onto the skin at the poration site and thus creates a positive pressure gradient in the biological fluid harvested from the tissue TS, i.e. the skin, forcing it towards the micropores." Page 47, line 28 - page 48, line 2.
62. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:	"One aspect of the invention relates to methods for obtaining biological fluids for analysis/testing." Page 4, lines 6 - 7.
(a) placing a layer in contact with a surface of tissue; (b) forming at least one hole in the tissue;	"Porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte." Page 4, lines 14 – 16 "A sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collection from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 24 - 26.
(c) collecting biological fluid from the tissue through at least one opening in the layer; and	"A sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collection from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 24 - 26.

(d) wetting a sensor with biological fluid to measure a characteristic of the biological fluid and wherein the process further comprises the step of creating a negative pressure to the skin so as to induce flow of biological fluid through the opening.	"Wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid." Page 4, lines 22 - 24. "Applying force to the mechanical element 850 presses the integrated device onto the skin at the poration site and thus creates a positive pressure gradient in the biological fluid harvested from the tissue TS, i.e. the skin, forcing it towards the micropores." Page 47, line 28 - page 48, line 2.
63.An integrated fluid harvesting and analysis device, comprising:	As used herein, the term "integrated device" means a device suitable for forming small holes or micropores in tissue, collecting a biological fluid from the tissue (preferably through the micropores so created) and analyzing the biological fluid to determine a characteristic thereof. Page 21, lines 24-27.
(a) a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;	"...a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;" Page 23, lines 24-27.
(b) a sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid; and	"A sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 18-20.

(c) a mechanical element having a small opening therein and capable of receiving the integrated device such that the porating element is aligned with the small opening, the mechanical element responsive to downward force thereon to cause the surface of the tissue to bulge into the small opening.	"A mechanical element 850 is provided, having a small opening 852, 2 mm to 4 mm in diameter. The mechanical element 850 permits the integrated device to slide between two opposing surfaces and contains the integrated device. Applying force to the mechanical element 850 presses the integrated device onto the skin at the poration site and thus creates a positive pressure gradient in the biological fluid harvested from the tissue TS, i.e., the skin, forcing it towards the micropores where it can exit the tissue and enter the inlet port(s) of the fluid management chamber of the integrated device (100, 200, 300, 400, 600, 1000). The tissue bulges into the opening 852 as shown in FIG. 18. A close registration is maintained between the inlet ports to the integrated device and the micropores, which have been, or simultaneously will be, formed in the tissue directly beneath these ports. The mechanical device 850 may be optically clear on its top portion to allow for optical thermal ablation and optical reading of the photometric sensor in that form of the integrated device." Page 47, line 25- page 48, line 9.
64.An integrated fluid harvesting and analysis device, comprising:	"As used herein, the term "integrated device" means a device suitable for forming small holes or micropores in tissue, collecting a biological fluid from the tissue (preferably through the micropores so created) and analyzing the biological fluid to determine a characteristic thereof." Page 18, lines 24-27.
(a). a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;	"A first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue..." Page 23, lines 16-17.
(b). a sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid, and	"...a sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 18-20.

(c). sealing means for pneumatically sealing the integrated device to the surface of the tissue and forming a sealed chamber, and means coupled to the sealing means for supplying negative pressure to the sealed chamber.	"A sealing means in the form of a sealing assembly 800 is provided which comprises a perimeter base 802 that fits around the integrated device (100, 200, 300, 400, 600, 1000), and a top layer 804 that is sealed to the perimeter base 802, and extends above the integrated device. The sealing assembly 800 pneumatically seals around the integrated device to the surface of the tissue." Page 46, lines 5-10. "A vacuum port 808 is provided in the top layer 804 for connection to a means for supplying negative pressure, such as a pump 820 or other source of negative pressure, such as a syringe, a diaphragm or some portion of the chamber which can be flexed outward to increase the volume of the chamber and thereby reduce the pressure within the chamber or the like." Page 46, lines 14-18.

Appendix II-37 CFR 1.607(a)(6)

Claims in present application	Claim Language from claims filed in parent application in March 2001
1. A method for obtaining interstitial fluid for diagnostic testing comprising:	"143. A method for obtaining a sample of interstitial fluid for a diagnostic test, said method comprising the steps of:"
(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;	"(b) forming an unobstructed opening in the treated area of the skin"
(b) collecting a sample from the opening, wherein step (b) is enhanced by applying a vacuum to the selected area of the skin.	"(c) extracting the sample of interstitial fluid from the unobstructed opening in the skin, with the aid of vacuum and stretching of the skin."
2. A method for obtaining biological fluid for diagnostic testing comprising:	"204. A method for obtaining a sample of blood for a diagnostic test, said method comprising the steps of:"
(a) forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;	"(a) forming an unobstructed opening in an area of skin from which said sample is to be extracted."
(b) extracting the sample from the opening, wherein at least one positive and negative pressure are employed in order to enhance the extraction of the sample.	"(b) extracting said sample from said unobstructed opening in said area of said skin, with the aid of (1) a vacuum generated by a pump operated to maintain a desired level of vacuum."
3. The method of claim 2 wherein the biological fluid comprises blood.	"204. A method for obtaining a sample of blood for a diagnostic test, said method comprising the steps of:"

4. The method of claim 2 wherein the biological fluid comprises interstitial fluid.	"143. A method for obtaining a sample of interstitial fluid for a diagnostic test, said method comprising the steps of: (a) treating an area of the skin with vacuum or heat or both vacuum and heat to increase the availability of interstitial fluid at that area of the skin; (b) forming an unobstructed opening in the treated area of the skin; and (c) extracting the sample of interstitial fluid from the unobstructed opening in the skin, with the aid of vacuum and stretching of the skin."

Appendix III-Benefit Analysis

Claim 61	**Exemplary Disclosure from U.S. Patent No. 5,458,140**
A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:	"An object of the present invention is to provide a method for enhancing the transdermal and/or transmucosal withdrawal of analytes out from the body to be collected externally." Col. 4, lines 32 - 35.
(a) placing a layer in contact with a surface of tissue;	"The pad or reservoir is held in place,..., on the selected area of the skin surface." Col. 17, lines 24-26.
(b) forming at least one hole in the tissue;	"A further aspect of the invention is the use of ultrasound energy, optionally with modulations of frequency, intensity and/or phases, to controllably push and/or pump molecules through the stratum corneum via perforations introduced by needle puncture, hydraulic jet, laser, electroporation, or other methods." Col. 5, lines 13 - 18.
(c) collecting biological fluid from the tissue through at least one opening in the layer; and	"Another object of the invention is to controllably collect analytes from within the body through perforations in the stratum corneum, to enable the monitoring of these analytes." Col. 4, lines 36 - 38.

(d) wetting a sensor with biological fluid to measure a characteristic of the biological fluid, wherein the process further comprises applying positive pressure to the layer so as to induce flow of biological fluid through the opening.	"If the analysis is to take place at the site of collection, a number of well known techniques for measurement of analytes of clinical relevance can be used. These techniques might include, for example, chemical, immunochemical, and iontophoric techniques. The non-disposable unit can include, in the collection reservoir, chemicals or immunochemicals that react with the analyte of interest." Col. 6, lines 13 - 24. "A further aspect of the invention is the use of ultrasound energy, optionally with modulations of frequency, intensity and/or phases, to controllably push and/or pump molecules through the stratum corneum via perforations introduced by needle puncture, hydraulic jet, laser, electroporation, or other methods." Col. 5, lines 13 - 18.

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ATTORNEY DOCKET NO. 19141.0016U2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Eppstein, *et al.*	)	
	)	Group Art Unit:
Serial No. 10/084,763	)	
	)	
Filed: February 21, 2002	)	Anticipated Examiner: P. Wingood
	)	
For: **"INTEGRATED TISSUE PORATION, AND FLUID HARVESTING"**	)	

REQUEST FOR SECOND INTERFERENCE PURSUANT TO 37 CFR 1.607

Assistant Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
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April 15, 2002

Sir:

In accordance with the provisions of 37 C.F.R. §1.607, Applicants' hereby request that an interference be declared between this application and unexpired U.S. Patent No. 6,071,251.

In accordance with the provisions of 37 C.F.R. 1.607(a)(1)- (a)(6), Applicants' offer the following:

(1) The patent at issue is U.S. Patent 6,071,251 issued June 6, 2000. The patent is assigned, on its face, to Abbott Laboratories.

(2) The proposed count is as follows:

Claims 5, 6, 7, 9 or 38 of this application; or Claims 1, 13, or 25 of U.S. Patent 6,071,251.

(3) Claims 1-31 of U.S. Patent 6,071,251 correspond to the proposed count:

(4) Claims 5-10 and 38-39 of this application correspond to the proposed count;

(5) The terms in claims in this application identified as corresponding to the count can be applied to Applicants' specification as shown in Appendix I attached hereto.

(6) Applicants have met the requirements of 35 U.S.C. 135(b). Attention in this regard is directed to Claims 112-142 filed in a Preliminary Amendment in parent application Serial No. 09/263,464 on March 15, 2001.

In considering 35 USC 135(b), Applicants would point out that each of the claims in the '251 patent were copied into the parent application Serial No. 09/263,464 on March 15, 2001, which date is prior to the one year anniversary of issuance of the patent. Attention is further directed to the claim chart appearing in Appendix II where the present claims 5, 6, 9 and 10 are compared with claims 112, and 124, which claims were offered in parent application 09/263,464 on March 15, 2001.

Applicants hereby request benefit of the effective filing date of November 15, 1993 in the declaration of interference as evidenced by the disclosure in their prior applications[1]. In connection with this effective filing date, Applicants would point out:

[1] This application is the latest in a chain of applications which include U.S. application Serial No. 09/570,334, filed May 15, 2000, U.S. application Serial No. 09/208,166, filed December 9, 1998 (now U.S. Patent No. 6,142,939), U.S. application Serial No. 08/776,863, filed September 5, 1997 (now U.S. Patent No. 5,885,211), U.S. application Serial No. 08/520,547, filed August 29, 1995 (now abandoned), U.S. application Serial No. 08/152,442, filed November 15, 1993 (now U.S. Patent No. 5,458,140). This application is also the latest in a chain of applications which include U.S. application Serial No. 08/152,174, filed December 8,

First, Applicants are entitled to benefit of their earlier filed applications for purposes of this interference, if the count reads on at least one adequately disclosed embodiment in the earlier application. Weil v. Fritz, 572 F.2d 856, 865-66 n.16, 196 USPQ 600, 608 n.16 (CCPA 1978). Evidence of this, involving Claim 7 and the disclosure of the '140 patent that issued from application Serial No. 08/152,442 filed November 15, 1993, is provided in Appendix III to this request.[2]

Second, as to the requirements of 37 C.F.R. §1.608, the effective filing date, i.e., November 15, 1993, of the present application is more than three years **earlier** than the earliest possible effective filing date of the patent in question, i.e., December 6, 1996. Accordingly, Applicants submit that no showing under 37 C.F.R. §1.608 is required.

Third, in light of their earlier effective filing date, Applicants should also be designated as the senior party in the interference.

1993 (now U.S. Patent No. 5,445,611); and U.S. Provisional Application No. 60/008,043, filed October 30, 1995. Finally, this application is also the latest in a chain of applications including U.S. application Serial No. 09/263,464, filed March 5, 1999, and U.S. Provisional Application No. 60/077,135, filed March 6, 1998.

[2] The citations are offered in connection with the '140 patent solely due to the relative ease of citing to the column and line numbers of the patent, however, the cited disclosure is the same as that of the '442 application as filed.

As a final matter, should the Examiner have any questions regarding this paper, or the application in general, he is invited to telephone the undersigned at his earliest convenience. No fee is believed due. However, the Commissioner is hereby authorized to charge any fees that may be required to the Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF EXPRESS MAIL

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail No. EL924194186US in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date indicated below.

David Thorpe

4/15/02
Date

Appendix I- 37 CFR 1.607(a)(5)

Applicants' Claims corresponding to the proposed count	Exemplary Disclosure in Applicants' Specification
5. A multi-layer integrated device comprising:	"The integrated device 100 comprises a substrate layer 110." Page 24, lines 19-20. "A layer of photothermal material 130 is provided on the bottom surface of the substrate 110." Page 24, lines 25-26.
(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;	"A layer of photothermal material 130 is provided on the bottom surface of the substrate 110 or directly applied to the tissue surface from which biological fluid is to be collected." Page 24, lines 25-27.
(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid; and	"An analyte sensor 120 is disposed on the under-surface of the substrate layer 110." Page 24, lines 21-22. "An analyte assay system is shown at reference number 10." Page 24, lines 16-17.
(c) a substrate layer that is capable of being in contact with a processing circuit, wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the sensor (b); and further wherein said substrate layer (c) has at least one opening therein.	"The integrated device 100 has electrode leads 122 that connect to the analyte sensor 120 and to a processing circuit 20." Page 24, lines 23-24. *See also* Fig. 1. "The mesh 140 acts by a surface tension mechanism to move the biological fluid to the sensor." Page 28, lines 3-4. "The integrated device 100 comprises a substrate layer 110 that includes an optically transparent window 112 on at least a portion thereof." Page 24, lines 19-21.

6. A multi-layer integrated device comprising:	"The integrated device 100 comprises a substrate layer 110." Page 24, lines 19-20. "A layer of photothermal material 130 is provided on the bottom surface of the substrate 110." Page 24, Lines 25-26.
(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;	"A layer of photothermal material 130 is provided on the bottom surface of the substrate 110 or directly applied to the tissue surface from which biological fluid is to be collected." Page 24, lines 25-27.
(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;	"An analyte sensor 120 is disposed on the under-surface of the substrate layer 110." Page 24, lines 21-22. "An analyte assay system is shown at reference number 10." Page 24, lines 16-17.
(c) a substrate layer that is capable of being in contact with a processing circuit, and	"The integrated device 100 has electrode leads 122 that connect to the analyte sensor 120 and to a processing circuit 20." Page 24, lines 23-24. *See also* Fig. 1.
(d) a bottom layer; wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and wherein said substrate layer (c) has at least one opening therein.	"A layer of photothermal material 130 is located on the bottom surface of the substrate 110." Page 24, lines 25-26. "The integrated device 100 comprises a substrate layer 110 that includes an optically transparent window 112 on at least a portion thereof." Page 24, lines 19-21.
7. An integrated device comprising:	"The integrated device 100 comprises a substrate layer 110." Page 24, lines 19-20. "A layer of photothermal material 130 is provided on the bottom surface of the substrate 110." Page 24, Lines 25-26.

(a) a pad capable of receiving and transporting a biological sample containing an analyte;	"Such sensors are well known in the art, and include assay pads." Page 28, lines 19-20. A collection/reaction pad 2234 on the interior of the device 2206 is positioned with respect to the opening in the lower section 2222 so that glucose entering the device 2206 from the skin is collected by the pad 2234. Page 105, lines 8-10. The collecting pad 2190 serves as a reservoir for collection of the analyte. Page 109, lines17-18.
(b) a detector for detecting the presence and/or quantitating the concentration of analyte in the sample, said mechanism capable of being in contact with a display for illustrating results of the detector; and	"The hand-held unit 500 includes processing circuitry that electrically couples to the electrodes 432 and 434 to obtain an assay measurement from the sensor 420." Page 37, lines 8-10. "The integrated device 400 is designed for use with a hand-held unit 500 that processes assay measurements obtained by the integrated device 400 and displays the measurements on a display 510." Page 36, lines 18-20. In this illustrative embodiment, glucose is the analyte to be collected and assayed by the glucose oxidase reaction described previously. A color reaction develops as the analyte is collected. Page 104, last three lines.
(c) a strap or adhesive tape for holding the pad to an area of skin surface, wherein the integrated device contains at least one opening suitable to allow the biological sample to contact the pad.	In addition, a layer of adhesive may be applied to certain bottom surfaces of the substrate 110 to hold the integrated device onto the tissue surface Page 24, last line to page 25, line 1. The pad or reservoir is held in place, either passively or aided by appropriate fastening means, such as a strap or adhesive tape, on the selected area of skin surface. Page 104, lines 8-10.

8. The integrated device of claim 7 wherein the pad contains a surfactant to facilitate transport of the sample across the pad.	"The mesh 140 may be treated with a surfactant compound as well. The technique of treating a wicking mesh layer with surfactants to transport a fluid to an assay sensor is known in the art." Page 28, lines 7-12.
9. An integrated device for removing and testing a biological sample from the skin comprising:	"The integrated device 100 comprises a substrate layer 110." Page 24, lines 19-20. "A layer of photothermal material 130 is provided on the bottom surface of the substrate 110." Page 24, Lines 25-26.
(a) a lower section having at least one opening therein;	"A layer of photothermal material 130 is located on the bottom surface of the substrate 110." Page 24, lines 25-26. "The integrated device 100 comprises a substrate layer 110 that includes an optically transparent window 112 on at least a portion thereof." Page 24, lines 19-21.
(b) a pad capable of collecting and transporting a biological sample containing an analyte; and	"Such sensors are well known in the art, and include assay pads." Page 28, lines 19-20.
(c) a detector for determining the presence and/or quantity of the analyte, said detector capable of being in contact with a display for the results of the detector.	"The hand-held unit 500 includes processing circuitry that electrically couples to the electrodes 432 and 434 to obtain an assay measurement from the sensor 420." Page 37, lines 8-10. "The integrated device 400 is designed for use with a hand-held unit 500 that processes assay measurements obtained by the integrated device 400 and displays the measurements on a display 510." Page 36, lines 18-20.

10. The integrated device of claim 9 wherein the pad contains a surfactant to facilitate transport of the sample across the pad.	"The mesh 140 may be treated with a surfactant compound as well. The technique of treating a wicking mesh layer with surfactants to transport a fluid to an assay sensor is known in the art." Page 28, lines 7-12.
38.An integrated fluid harvesting and analysis device, comprising:	"The integrated device 100 and all other specific embodiments described hereinafter, are designed to form micropores in tissue, collect fluid from the tissue, and analyze the fluid in a single (integrated) step." Page 25, lines 12 - 14.
(a) a first layer for positioning in contact with tissue and through which poration of tissue is achieved such that at least one opening is formed in the first layer and at least one opening is formed in the tissue;	For example, the integrated device can comprise at least a first layer that supports a porating element, and which is to be placed in physical contact with the tissue surface. Page 10, line 15-17. "The integrated device 100 and all other specific embodiments described hereinafter, are designed to form micropores in tissue, collect fluid from the tissue, and analyze the fluid in a single (integrated) step." Page 25, lines 12 - 14.
(b) a sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid.	"A sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collection from the tissue to provide an indication of a characteristic of the biological fluid." Page 23, lines 24 - 26.
39. The device of claim 38, and further comprising a second layer overlying the first layer, the sensor being positioned between the first layer and the second layer.	"An optional second layer overlies the first layer with a space therebetween. A sensor can be disposed between the first and second layers, or otherwise at a location on or about the first layer so as to be wetted for harvesting biological fluid." Page 10, lines 17-19.

Appendix II- 1.607(a)(6)

Claims in present application	Claim language from claims filed in parent application in March 2001
5. A multi-layer integrated device comprising:	"112. A multiple-layer article comprising:"
(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;	"(a) a layer capable of receiving blood and transporting blood by means of chemically aided wicking."
(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid; and	"(b) a layer capable of detecting the presence of analyte or measuring the amount of analyte in blood."
(c) a substrate layer that is capable of being in contact with a processing circuit, wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the sensor (b); and further wherein said substrate layer (c) has at least one opening therein.	"(a) a layer capable of receiving blood and transporting blood by means of chemically aided wicking." "(c) a layer that can be placed in contact with a meter, the meter contactable layer overlying the blood transporting layer, said layer (a) capable of transporting blood to said layer (b), wherein said meter-contactable layer has at least one opening therein."
6. A multi-layer integrated device comprising:	"124. A multiple-layer article comprising:"
(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;	"(a) a covering layer" "(b) a layer overlying the covering layer, capable of receiving blood through the opening in the covering layer and transporting blood by means of chemically aided wicking."
(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;	"(d) a layer capable of detecting the presence or [*sic*] analyte or measuring the amount of analyte in blood."
(c) a substrate layer that is capable of being in contact with a processing circuit, and	"(c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood transporting layer"

(d) a bottom layer; wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and wherein said substrate layer (c) has at least one opening therein.	"(c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood transporting layer" "(d) a layer capable of detecting the presence of analyte or measures the amount of analyte in blood, which layer is disposed between the covering layer and the meter-contactable layer and is capable of receiving blood from the flood-transporting layer, wherein said meter-contactable layer has at least one opening therein."
9. An integrated device for removing and testing a biological sample from the skin comprising:	"124. A multiple layer article comprising:"
(a) a lower section having at least one opening therein;	"(a) a covering layer having an opening therein"
(b) a pad capable of collecting and transporting a biological sample containing an analyte; and	"(b) a layer, overlying the covering layer, capable of receiving blood through the opening in the covering layer and transporting blood by means of chemically aided wicking"
(c) a detector for determining the presence and/or quantity of the analyte, said detector capable of being in contact with a display for the results of the detector.	"(d) a layer capable of detecting the presence or [sic] analyte or measuring the amount of analyte in blood"
10. The integrated device of claim 9 wherein the pad contains a surfactant to facilitate transport of the sample across the pad.	"(b) ...transporting blood by means of chemically aided wicking."

Appendix III- Benefit Analysis

Claim 7	Exemplary Disclosure from U.S. Patent No. 5,458,140 1993
An integrated device comprising:	"Alternatively, the mechanism for quantitating the analyte can be build into the device used for collection of the analyte, either as an integral portion..." Column 17, lines 41-44.
(a) a pad capable of receiving and transporting a biological sample containing an analyte;	A collection/reaction pad 234 on the interior of the device 206 is positioned with respect to the opening in the lower section 222 so that glucose entering the device 206 from the skin is collected by the pad 234. Column 20, lines 52-55. The collecting pad 2190 serves as a reservoir for collection of the analyte. Column 20, lines 3-5.
(b) a detector for detecting the presence and/or quantitating the concentration of analyte in the sample, said mechanism capable of being in contact with a display for illustrating results of the detector; and	In this illustrative embodiment, glucose is the analyte to be collected and assayed by the glucose oxidase reaction described previously. A color reaction develops as the analyte is collected. Column 20, lines 38-41.
(c) a strap or adhesive tape for holding the pad to an area of skin surface, wherein the integrated device contains at least one opening suitable to allow the biological sample to contact the pad.	The pad or reservoir is held in place, either passively or aided by appropriate fastening means, such as a strap or adhesive tape, on the selected area of skin surface. Column 17, lines 24-26.